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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

January 23, 2004

WARNING LETTER NO. 2004-NOL-13

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Norwood O. Cain, President
Waterfront Seafood Company, Inc.
14358 Shellbelt Road
Bayou La Batre, Alabama 36509

Dear Mr. Cain:

On September 9 - 10 and 15, 2003, we inspected your seafood processing facility, located at 14358 Shellbelt Road, Bayou La Batre, Alabama. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or to otherwise operate in accordance with the requirements of this part, renders the fishery products of that processor adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(4)]. Accordingly, your ready-to-eat, cooked, picked crabmeat is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviations are as follows:

1. You must implement the monitoring procedures that you have listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the Rolling boil/Cooking time procedures at the cooking critical control point to control the pathogen survival hazard listed in your HACCP plan for processed blue crabmeat. Specifically, actual cooking time was not recorded during cooking operations on September 9, 2003. Instead, when cooking began, a projected end of cook time was calculated and recorded in the log.

2. Since you have included corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plans for ready-to-eat, cooked, picked crabmeat at the "Backing", "Backed Crab and

Claw Cooling", "Backed Crab and Claw Cooler", "Picking and Packing", and "Finished Product Storage" critical control points (CCPs) to control pathogen growth and toxin formation are not appropriate because the corrective action plans do not list the disposition of the product if it is found to exceed acceptable exposure levels.

3. You must monitor adequately sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor sufficiently the following areas of sanitation:

   a. Your firm failed to adequately monitor the prevention of cross contamination from insanitary objects to food as evidenced by:

      - The use of a hose that had been stored on the floor and contained a black and green mold-like substance. During backing operations on September 10, 2003, the hose was picked up off the floor and water flowed through the hose and over the black and green substance and onto cooked crabs on the backing table.

      - The presence of a brown, slimy residue in the PVC pipe supplying water inside the crab tumbler. Water came into contact with the brown residue and then with cooked crabs.

   b. Your firm failed to adequately monitor the condition and cleanliness of food contact surfaces as evidenced by:

      - Use of residue encrusted, etched-handled knives during processing. Two employees routinely contacted these knives and then contacted cooked, ready-to-eat crab claws without first washing or sanitizing their hands or gloves.

      - Use by backing employees of a residue encrusted, metal rake that repeatedly contacted cooked crabs.

      - Use of a crab tumbler that contained crab parts from previous operations.

   c. Your firm failed to adequately control employee health conditions that could result in the microbiological contamination of food. Specifically, during picking operations, an employee was observed to cough several times over cooked, ready-to-eat crabs, open containers of cooked crabmeat, and cooked crab parts.

   d. Your firm failed to adequately exclude pests from the food plant as evidenced by three live frogs and four live flies in the cooking/backing room during processing on September 10, 2003. Some of the flies landed on food contact surfaces, and one frog was observed in a perforated cooking basket. Immediately after these flies and frog were observed, and without first sanitizing and washing the food contact surfaces, ready-to-eat, cooked crabmeat came in contact with these food contact surfaces.

We may take further action if you do not correct these violations promptly. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that during our inspection your employee, Mr. Tommy Cain, made a verbal commitment to correct the observed deviations. However, please respond in writing within 15 working days from your receipt of this letter, outlining the specific actions you have taken to correct the deficiencies and to assure us that such violations will not recur. You should include in your response documentation such as copies of your cooking log or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at 504-253-4519.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483